IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

OMAR NIEVES-ORTIZ, *et al.*, **Plaintiffs,** v. CORPORACION DEL CENTRO CARDIOVASCULAR DE PUERTO RICO Y DEL CARIBE, *et al.*, **Defendants.**	**CIVIL NO.** 21-1010 (JAG)

OPINION AND ORDER

GARCIA-GREGORY, D.J.

Pending before the Court are (i) Defendant Edgardo Hernández Vila's ("Hernández") Motion to Dismiss pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b), Docket No. 134; (ii) Defendant Cardiovascular and Critical Services, PSC's ("CCS") Motion to Dismiss the Amended Complaint pursuant to Rule 12(b)(6), Docket No. 161; (iii) Defendants Medtronic Puerto Rico Operations Co. and Medtronic, Inc.'s (collectively "Medtronic") Motion to Dismiss Relator's Amended Complaint, Docket No. 162; (iv) Defendant Emergenciólogos para Puerto Rico's ("EPR") Motion to Dismiss, Docket No. 178; (v) Defendant Corporación del Centro Cardiovascular de Puerto Rico y del Caribe's ("CCCPR") Motion to Dismiss Relator's Amended Complaint, Docket No. 180; (vi) and Defendants Heart Rhythm Management, PSC ("Heart Rhythm Management") and Juan Carlos Sotomonte-Ariza's ("Sotomonte") Motion to Dismiss Relator's Amended Complaint, Docket No. 181 (collectively the "Motions to Dismiss").

Omar Nieves-Ortiz ("Relator") brought this *qui tam* action alleging the following violations of the False Claims Act ("FCA"), 31 U.S.C. § 3729: presentation of false claims in violation of §

3729(a)(1)(A) (Counts I, IV, and VII); use of false statements in violation of § 3729(a)(1)(B) (Counts II, V, and VIII); and conspiracy to commit these acts in violation of § 3729(a)(1)(C) (Counts III, VI, and IX). Docket No. 123 at 59-66. Defendants request dismissal, arguing that (i) the claims are partially, if not fully, time barred; (ii) the claims are barred under the doctrine of public disclosure; (iii) the claims are barred by *res judicata*; (iv) the Amended Complaint does not adequately allege a FCA violation; and (v) the Amended Complaint fails to meet Fed. R. Civ. P. 9(b)'s heightened pleading standard. Docket Nos. 134 at 2-5, 22-25; 161 at 5-7, 16, 21-26; 162 at 17-21, 22-30; 178 at 3, 11-16; 180 at 3, 5-11; 181 at 3-9, 14-24. The Court shall address each in turn.

FACTUAL BACKGROUND

Medicare and Medicaid are health insurance programs administered by the United States Government and funded through taxpayer revenue. Docket No. 123 at 7-8. The United States Department of Health and Human Services, through the Centers for Medicare and Medicaid Services, administers and supervises these federal health care programs. *Id.* Providers submit claims for payment through Medicare and Medicaid in accordance with provider agreements between the physicians and hospitals with the Centers for Medicare and Medicaid Services. *Id.* at 9. Providers must comply with federal and state antikickback statutes. *Id.*

CCCPR is a public corporation that operates the hospital Centro Cardiovascular del Puerto Rico y del Caribe (the "Hospital"). *Id.* at 5, 16. The Hospital serves as a "specialized center for cardiac diseases," in which only "general cardiologists, interventional cardiologists, cardiac electrophysiologists, heart failure cardiologists, cardiothoracic surgery, and peripheral vascular surgeons" have admitting privileges. *Id.* at 17. EPR is a for-profit corporation that administers CCCPR's emergency room. *Id.* at 6.

Electrophysiologists specialize in the treatment of cardiac rhythm disorders. *Id.* at 17. Electrophysiologists rarely receive new patients directly and are primarily dependent upon referrals from emergency room physicians. *Id.* at 18. Per the Relator, it is "customary" for the referring physicians to refer patients "directly to the sales representative/technicians of the [Electrophysiology Medical Device ("EMD")] companies, who in turn direct the patient to the electrophysiologist of their choosing." *Id.* CCCPR "bills federal health care programs for the EMDs contracted through Requests for Proposals [("RFP")] and implanted by electrophysiologists on their patients in the Hospital." *Id.* at 17.

The EMD companies assign sales representatives and technicians to promote their devices in set geographic regions. *Id.* at 19. The sales representatives additionally provide "technical advice and follow-up services such as device monitoring, programming, and follow-up of implanted devices," which requires them to regularly visit treating physicians' offices and have direct contact with patients. *Id.* "Private cardiologists rely heavily on salespeople or technicians for these crucial services to their patients," which leads to long-term working and personal relationships between the sales representative and the referring physicians *Id.* at 19-20. This follow-up care is billed to federal healthcare programs such as Medicare and Medicaid. *Id.* Medtronic manufactures and sells EMDs for the diagnosis and treatment of heart rhythm disorders. *Id.* at 6. Hernández was Medtronic's sales representative assigned to CCCPR at the time of the events underlying this action. *Id.* at 6-7, 21. Hernández had previously worked at Boston Scientific. *Id.* at 25.

Sotomonte is a cardiologist who specializes in electrophysiology. *Id.* at 5. Sotomonte worked as a private electrophysiologist with CCCPR while Hernández worked for Boston Scientific. *Id.* at 25. The Relator is a cardiologist, internist, and clinical cardiac electrophysiologist.

Id. at 5. "The Relator's involvement with the CCCPR began as a Cardiology Fellow of the University of Puerto Rico, School of Medicine, from July 2006 through July 2009." *Id.* at 25. It is during this time that the Relator met Sotomonte and Hernández. *Id.* The Relator alleges that during his fellowship, Hernández would invite the cardiology fellows and referring physicians to food and drinks. *Id.* Per the Relator, Hernández told him to "send [Hernández] a case[,]I will send it to Dr. Sotomonte." *Id.* Even though electrophysiologists with CCCPR were permitted to choose from three companies—Medtronic, Boston Scientific, and St. Jude Medical—that supplied EMDs,

> every time the Relator came across a patient who needed an EMD, he always called Mr. Hernández first, who in turn referred the patient to Dr. Sotomonte. From what the Relator gathered, the way to ensure that patients received care and the medical device they needed was by first calling the seller of the device, in this case, Mr. Hernández . . . During the occasions that the Relator joined Dr. Sotomonte, he always saw Mr. Hernández in the operating room . . . Dr. Sotomonte was implanting the devices sold by Mr. Hernández'[s] company, regardless of the supplier. The Relator never saw other electrophysiologists exclusively implanting the devices sold by Mr. Hernández's company.

Id. at 25-26.

Sotomonte later became President of the Medical Staff and President of the Executive Committee of the Medical Staff in 2010. *Id.* at 22. In July 2011, CCCPR announced an RFP to purchase EMDs. *Id.* at 28. "The RFP covered EMDs that are paid by the Hospital directly to the medical device company and later billed in bundles to Medicaid plans, Medicare, Medicare Advantage plans, and a few private health insurance plans." *Id.* The EMDs from the company selected were to be assigned to physicians for patient care. *Id.* The Relator alleges that, even though Sotomonte was not a member of the committee tasked with evaluating the proposals,

> he participated in the process of evaluating the proposals . . . advis[ed] the Committee on which company or companies submitted the best proposal . . . met with the representatives of the companies [ ] and discussed with their

> representatives their respective proposals[, and] met with the members of the Committee to advise them on which company submitted the best proposal . . . .

Id. at 29. Notwithstanding, the Executive Director, informed by the recommendation of the committee, has the ultimate authority to award the contract following an RFP process. *Id.* at 38. The Amended Complaint contains no allegations that Sotomonte discussed the RFP process with the Executive Director, or that Sotomonte influenced the Executive Director's final decision. While not the lowest bidder amongst the 2012 RFP participants, Medtronic was awarded the contract, which was formalized on November 8, 2011. *Id.* at 30. This contract with Medtronic had a two-year term. *Id.* at 32. Prior to this contract, the Hospital purchased 60% of its EMDs from Medtronic. *Id.* at 30.

In early 2012, Sotomonte organized and served as program chair for the First Electrophysiology Symposium of the Puerto Rico Chapter of the American College of Cardiology. *Id.* at 30-31. As program chair, Sotomonte was responsible for coordinating the scientific program, funding, and organization of the event. *Id.* The Symposium was sponsored by Medtronic. *Id.* That same year, the Relator returned to CCCPR and the Hospital as an electrophysiologist. *Id.* at 25. Upon his return, the Relator noted that "electrophysiologists were no longer free to choose the supplier of the EMDs to use with their patients. Instead, they were obligated to implant devices sold by Medtronic." *Id.* at 26. Per the new policy adopted in 2011, the Admissions Department of the Hospital selected the EMDs as opposed to the electrophysiologists. *Id.* at 26, 28. At some point during 2012, Sotomonte served as Interim Medical Director while the Medical Director José Novoa Loyola "was away." *Id.* at 22. During his term as Interim Medical Director, Sotomonte "directed a program to transfer patients in need of invasive cardiology procedures, including

electrophysiology procedures, from Doctors Center Hospitals." *Id.* at 27. The Relator alleges that "Sotomonte received practically 100% of those referrals." *Id.*

Sotomonte organized and served as chair for the 2013 Second Electrophysiology Symposium of the Puerto Rico Chapter of the American College of Cardiology. *Id.* at 31. Medtronic again provided sponsorship. *Id.* On April 16, 2013, an article was published in *El Nuevo Día* newspaper—allegedly at Medtronic's behest—promoting Sotomonte's private practice. *Id.* On July 11, 2013, the Relator held a meeting with Medtronic's Puerto Rico Cardiac Rhythm General Manager Alberto Ysunza to discuss his concerns that Hernández was referring all his patients to Sotomonte and was "making disparaging comments about the Relator to discourage referring physicians from sending him patients." *Id.* at 30. The Amended Complaint does not expand upon what the alleged disparaging comments entailed. The Relator also alleges that Hernández went so far as to "confront[] a private cardiologist and question[] him for having referred a case to the Relator instead of Dr. Sotomonte." *Id.* at 33.

A second RFP was announced in 2014. *Id.* at 32. The 2014 committee was mostly composed of the same members from the 2011 committee. *Id.* The Relator contends that Sotomonte participated in the process as he had done before. *Id.* at 32-33. Two contracts were awarded: one with Boston Scientific and the other with Medtronic. *Id.* Boston Scientific and Medtronic were each bestowed 50% of the purchases for EMDs. *Id.* As with the 2012 contracts, the 2014 contracts had a term of two years. *Id.* at 34. In addition to sales covered under the contract, "Medtronic received revenue from the implantation of its EMDs in patients covered by insurance plans that fell outside the scope of the RFP. For those patients, the physicians were free to select an EMD from any of the three primary manufacturer companies." *Id.* at 33. Sotomonte "almost universally"

selected Medtronic devices for such patients. *Id.* Furthermore, "sometime in 2014, Medtronic signed a Contract with Dr. Sotomonte and CCCPR for research and development funded by Medtronic or its related companies." *Id.* at 30.

On June 10, 2015, while serving as President of the Medical Staff and Director of CCCPR's Invasive Laboratory, Sotomonte announced the introduction of a "Transfer Program" to facilitate the transfer of patients who required invasive cardiology procedures from Doctor's Center Hospital to CCCPR. *Id.* at 42. When the Relator questioned Sotomonte specifically as to how patients who required electrophysiology services were to be assigned, Sotomonte did not respond. *Id.* at 43. Following the meeting, on June 23, 2015, the Relator extended an offer to share his office at CCCPR with Jaime Aponte, a UPR Cardiology Training Program student set to graduate shortly. *Id.* Aponte declined and explained that Sotomonte had already offered him a business arrangement. *Id.*

Sotomonte became the Acting Medical Director of the CCCPR on July 16, 2015, and was officially offered the position of Medical Director in August 2015 following a vote by the Board of Directors. *Id.* at 23. Sotomonte ceased serving as President of the Medical Staff and President of the Executive Committee of the Medical Staff. *Id.* at 22. On August 14, 2015, CCCPR and Doctor's Center Hospital signed a contract implementing the Transfer Program. *Id.* at 43. On August 17, 2015, CCCPR signed a contract with Aponte's newly minted corporation CCS. *Id.* The contract established that CCS would manage the Transfer Program and granted CCS the power to determine when Doctor's Center Hospital patients would be transferred to CCCPR for invasive cardiology procedures. *Id.* Per the contract, CCS maintained exclusive control of the management and billing of cardiology services at Doctor's Center Hospital. *Id.* at 44. CCS was compensated

$480,000 yearly, "with the right of CCS to bill directly to the patient's health insurance for the services rendered that surpassed the $480,000.00 payment threshold." *Id.* at 43-44. Between August 14, 2015, and October 1, 2015, CCCPR and Doctor's Center Hospital entered into four such Transfer Program contracts, covering the four Doctor's Center Hospital on the island. *Id.* at 44-45. "These Hospitals would also be barred from accepting new applications to their cardiology faculty unless the providers were under contract with the CCCPR and members of its faculty." *Id.*

The Transfer Program established a protocol in which a patient who arrived at Doctor's Center Hospital and required an evaluation by a cardiologist would be evaluated by a CCS cardiologist. *Id.* at 44. If the evaluating cardiologist determined the patient required an invasive cardiovascular procedure, a transfer to the Hospital would be initiated. *Id.* The evaluating/referring cardiologist would communicate directly with the subspecialist at CCCPR set to perform the procedure. *Id.* Patients who required invasive cardiological treatment were assigned to a cardiologist according to an on-call roster. *Id.* at 43-44. As CCCPR did not have an on-call program for electrophysiologist, they were referred directly to a physician, which per the Relator resulted in Sotomonte receiving most referrals. *Id.* The Relator alleges that

> neither [he] nor other electrophysiologists were invited to the meetings of the Invasive Laboratory for several years, during which details about the Transfer Program were discussed by Dr. Sotomonte and the interventional cardiologists who participated in the Program . . . Electrophysiologists, other than Dr. Sotomonte, were excluded from these meetings until 2018, when the Relator complained to the Director of the Invasive Laboratory, Dr. Edwin Pérez.

Id. at 45.[1] The Relator further alleges that Sotomonte "receive[d] around 80% of the patient referrals originating from the ER," which the Relator alleges "were directed to [Sotomonte] based in part on [his] ability to shape Hospital policies and practices to financially benefit Medtronic and other interested parties." *Id.* at 27. "Sometime in 2015-2016," a new RFP was issued. *Id.* at 34.

Sotomonte's appointment as Medical Director became effective October 1, 2015. *Id.* at 23. On February 1, 2016, CCCPR's contract with CCS was amended to increase CCS's yearly compensation from $480,000 to $720,000. *Id.* at 44. Because Sotomonte's appointment as Medical Director would mark the first time a member of the medical staff "with a private practice and office in the Hospital would also be the Medical Director of the facility," the appointment was subject to him obtaining a waiver from the Office of Governmental Ethics of the Commonwealth of Puerto Rico, as well as the following terms:

> a. Dr. Sotomonte was required to dedicate no less than 37.5 hours weekly to his duties as Medical Director;
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> b. Although he was allowed to continue his private practice at the Hospital, he was to be available at all times to perform his functions as Medical Director, unless he was required to attend to exigencies related to a patient, with such possible conflict brought immediately to the attention of the Executive Director of Centro Cardiovascular.
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> c. Dr. Sotomonte was to abstain from any intervention in the assignment of operating rooms for procedures if the use presented a conflict of any kind with respect to his private practice.

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[1] However, the Relator also claims that he "asked during the [June 10, 2025, Invasive Laboratory] meeting how [the patients] would be distributed, to which Dr. Sotomonte provided no answer." *Id.* at 43. Thus, he must have attended at least one Invasive Laboratory meeting, specifically the meeting in which the Transfer Program was announced.

> d. In situations which "could be interpreted as potentially being in an indirect or direct conflict with the above requirements," he was to bring the issue immediately to the attention of the Executive Director.

Id. at 23-24. The waiver was issued on April 22, 2016, "conditioned upon his abstention from activities that might present a conflict of interest (e.g., assignments of operating rooms), as well as a proviso limiting his private practice to no more than one day per week." *Id.* The Relator raises concerns that "Dr. Sotomonte continues to maintain a very active private practice at the Hospital, performing surgery virtually daily, and providing other Cardiac Electrophysiological services through his private company, [Heart Rhythm Management], and the private office he rents from the CCCPR." *Id.* Sotomonte's private practice "almost exclusively" employs Medtronic's EMDs for "patients who do not fall into the categories contemplated in the Contract awarded to Medtronic." *Id.* at 22.

A meeting of the Medical Staff was held on May 26, 2016. *Id.* at 47. During this meeting, the Relator requested information as to how the referrals to electrophysiologists were managed through the Transfer Program. *Id.* at 47. On July 1, 2016, the Relator voiced concerns with the RFP process, "particularly the lack of participation by other Cardiac Electrophysiologists and the lack of transparency." *Id.* at 34. The Relator sent a follow up letter to the then Executive Director Carlos Cabrera reiterating his request made to Sotomonte during the May 2016 meeting for information on the referral process.[2] *Id.* at 47. The Relator did not receive any response. *Id.* Another Medical Staff meeting was held on December 14, 2016, in which the Relator requested to participate in the

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[2] The Relator alleges that a pattern of retaliation commenced after this letter. *Id.* at 47. Nevertheless, the Relator does not raise a claim of retaliation in the Complaint, and there is currently a parallel pending action in this Court that raises retaliation claims. *See* Civ. No. 20-1717.

Transfer Program's on-call roster. *Id.* When Sotomonte responded that the Transfer Program only had an on-call program for interventional cardiologists, the Relator petitioned for the creation of an on-call program for the electrophysiologists as well. *Id.* Sotomonte replied that "the electrophysiologists have never wanted the creation of an on-call roster," and ultimately no such program was created. *Id.* The Relator subsequently met with Sotomonte, Aponte, Executive Director Carlos Cabrera, and a Dr. Daniel Arzola[3] on December 22, 2016, to again request the creation of an on-call program for the assignment of electrophysiologists to the patients referred from the Transfer Program. *Id.* at 47-48. The Relator expressed that it was "his impression, based on what he witnessed, that most, if not all, of the electrophysiology patients managed under the Transfer Program were being referred to Dr. Sotomonte." *Id.* Furthermore, the Relator voiced his opinion that CCS and/or its founder Aponte were referring "most, if not all," electrophysiology patients under the Transfer Program to Sotomonte due to his role in the creation of the Transfer Program and the assignment of the program's contract to CCS. *Id.* Sotomonte and Arzola rejected this request, and no such program was created. *Id.*

The 2016 RFP process was conducted in a manner similar to the prior RFP processes, but Sotomonte served as an official member on the Committee for the first time. *Id.* at 35. Boston Scientific and Medtronic were awarded contracts that split the purchases for EMDs, each receiving 50%. *Id.* Medtronic remained favored for the implantation of EMDs for patients not covered under the RFP. *Id.* The Relator alleges that "[i]n exchange, Medtronic Vascular paid

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[3] The Complaint does not make clear Dr. Daniel Arzola's position or role in this matter. *Id.* at 47. Furthermore, the Complaint notes that a Dr. Miguel Abreu was absent from the meeting and excluded from the email invitation. *Id.* at 48. It is also not clear what Abreu's role was and what meaning, if any, the Court should attribute to his absence.

$25,575.00 to Dr. Sotomonte in 2016 for 'research and development,' and Medtronic Vascular and Medtronic Inc. paid him $568.00 for food and beverage." *Id.*

On February 20, 2017, a meeting was held between the electrophysiologists to discuss the Transfer Program. *Id.* at 48. Then Executive Director Jorge de Jesús Rozas, Sotomonte, and Abreu attended this meeting. *Id.* The Relator restated his belief that Aponte and those contracted under CCS were referring the Transfer Program patients solely to Sotomonte due to his position as Medical Director and his role in awarding CCS the contract to run the program. *Id.* Again, the Relator suggested the creation of an on-call program for electrophysiologists; this time Abreu expressed support for the idea and Sotomonte conceded to continue discussions as to the creation of the on-call program in a subsequent meeting. *Id.* at 49. No such meeting was held. *Id.*

CCCPR and CCS entered into a new contract on July 1, 2017, that provided CCS the exclusive right "to manage and treat all the patients at the intensive care unit of two Doctors Center Hospital (Manatí and Carolina). CCS would be paid $420,000.00 a year by CCCPR for this contract. These contracts specifically provided for the billing to Medicare and Medicare Advantage Programs." *Id.* at 44. As with the prior contract, Aponte was to submit an invoice to CCCPR on behalf of CCS for the services rendered. *Id.* "During the four-year duration of the Transfer Program," the Relator alleges that he "did not receive any patient referrals from DCH facilities." *Id.* at 45. The Relator asserts that after his numerous complaints and the denials of his requests that the patients be equitably distributed among the electrophysiologists, the Transfer Program was canceled by Executive Director Jorge de Jesús Rozas in May 2018. *Id.* at 49.

On December 28, 2017, the Relator drafted a letter to the Regional Business Director of Medtronic Jorge Acevedo and the President of Medtronic Latin America Hugo Villegas,

expressing concern with Medtronic's employees "interference with his referring physicians and possible violations of 'federal health programs' and the Anti-Kickback [S]tatute [("AKS")]." *Id.* at 36. The Relator met with Acevedo on the same day to discuss the letter and his concerns. *Id.* Later, on February 19, 2018, Acevedo responded to the letter denying the Relator's allegations. *Id.* Three months later, the Relator met with Medtronic supervisors Daniel Medina and Fernando Cortes to discuss Hernández's "misconduct" and its impact on his medical practice. *Id.* Per the Relator, Medina stated that he was aware of Hernández's conduct and that Hernández had been reprimanded accordingly for "expos[ing] the company to liability." *Id.* "According to Mr. Medina, Mr. Hernández' sole response was that he was Medtronic's top EMD salesperson." *Id.*

In anticipation of the 2019 RFP process, on September 13, 2018, the Relator and two colleagues expressed their concerns to the Hospital's management regarding Sotomonte's involvement in the process. *Id.* at 37. Specifically, they noted that Sotomonte should not be the only cardiac electrophysiologist on the committee given his relationship with Medtronic. *Id.* The Relator again raised concerns with the RFP process at an Invasive Laboratory meeting held on September 26, 2018. *Id.* The Hospital's former Executive Director Jorge De Jesus Rozas waved away the Relator's concerns. *Id.* Following the meeting, on October 10, 2018, the Relator requested that the Hospital provide the criteria it employs to select the EMDs during the 2016 RFP process. *Id.* The Relator also requested the minutes of the meeting held on September 26, 2018. *Id.* On October 31, 2018, Sotomonte announced his recusal from the RFP process. *Id.*

During the 2019 RFP process, the Committee's President Sandra Soler noted that Medtronic's EMDs were priced higher than Abbott Labs and Boston Scientific devices. *Id.* at 39. Medtronic, Boston Scientific, and Abbott were each awarded a third of the contract share. *Id.* On

or around October 21, 2019, the Relator formally challenged this RFP process, again expressing concerns with this "imposition policy." *Id.* Subsequently, the Hospital eliminated the policy and "allowed the electrophysiologists to use their clinical judgment and choose the EMDs they understood were best suited for their patients." *Id.* "Mr. Hernández continued to send practically all his patient referrals to Dr. Sotomonte." *Id.* at 40.[4]

The Relator alleges three fraudulent schemes from the facts above: (i) the Medtronic kickback scheme, *id.* at 28-42; (ii) the Transfer Program scheme, *id.* at 42-50, and (iii) the emergency room scheme, *id.* at 51-58. The alleged Medtronic kickback scheme was "an unlawful, systematic scheme where Dr. Sotomonte influenced CCCPR's contracting processes to secure for Medtronic [] a large market share for the purchase of the EMDs used by CCCPR's electrophysiologists," in exchange for "unlawful kickbacks and illegal remuneration." *Id.* at 28. The Transfer Program scheme outlines alleged "unlawful influence" by Sotomonte over the contracting process between CCCPR and CCS/Aponte, "in exchange for an illegal compensation arrangement that included patient referrals." *Id.* at 42. Finally, the alleged emergency room scheme purports that Sotomonte as Medical Director approved EPR's contract to run CCCPR's emergency room and "ensured [the contract's] continuance and increase in value,[] in exchange" for "unattached patient referrals," which "knowingly caused the submission of thousands of false claims for payment to Federal Healthcare Programs." *Id.* at 55-56.

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[4] The Complaint goes on to cover conduct that occurred after the filing of the present action. *See* Docket No. 123 at 42. Nevertheless, the allegations as to Hernández's behavior do not go to any element of the FCA claims and, thus, the Court shall not delve into these allegations.

STANDARD OF REVIEW

A defendant may move to dismiss an action for failure to state a claim upon which relief can be granted pursuant to Fed. R. Civ. P. 12(b)(6). To survive dismissal under this standard, a complaint must allege "a plausible entitlement to relief." *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1967 (2007). According to *Twombly*, the complaint must state enough facts to "nudge [the plaintiff's] claims across the line from conceivable to plausible." *Id.*, 1974. Therefore, to preclude dismissal pursuant to Fed. R. Civ. P. 12(b)(6), the complaint must rest on factual allegations sufficient "to raise a right to relief above the speculative level." *Id.*, 1965.

At the motion to dismiss stage, courts accept all well-pleaded factual allegations as true, and draw all reasonable inferences in the plaintiff's favor. *See Correa-Martinez v. Arrillaga-Belendez*, 903 F.2d 49, 51 (1st Cir. 1988). Thus, plaintiff bears the burden of stating factual allegations regarding each element necessary to sustain recovery under some actionable theory. *Goolev v. Mobil Oil Corp.*, 851 F.2d 513, 514 (1st Cir. 1988). Courts need not address complaints supported only by "bald assertions, unsupportable conclusions, periphrastic circumlocutions, and the like." *Aulson v. Blanchard*, 83 F.3d 1, 3 (1st Cir. 1996).

ANALYSIS[5]

I. Timeliness

Medtronic, Heart Rhythm Management, and Sotomonte argue that the statute of limitations bars all FCA violations that occurred ten years prior to commencement of the present

[5] As Defendants' argument that the claim is barred under the public disclosure doctrine is an affirmative defense, rather than a jurisdictional bar, the Court need not address this assertion as a threshold matter. *See United States ex rel. Banigan v. PharMerica, Inc.*, 950 F.3d 134, 136 n.1 (1st Cir. 2020) ("The public disclosure

action, i.e., those predating January 8, 2011. Docket Nos. 162 at 22; 181 at 25. Conversely, Hernández contends that the "allegations [pertaining to him] are all time barred. Dr. Nieves' only personal knowledge-based allegations refer to acts which allegedly occurred while he was a Fellow (from July 2006 to July 2009) which fall out of the six-year FCA statute of limitations for *qui tam* actions." Docket No. 134 at 3. Similarly, CCS argues that "under the provisions of the FCA August 2015 [when the alleged fraudulent scheme involving CCS began] constitutes the moment at which the allegedly illegal kick back and remuneration scheme with CCS began," and thus the Relator had six years from said date to file, until August 2021. Docket No. 161 at 17, 19. As this action was commenced on January 8, 2021, *see* Docket No. 1, CCS and EPR reason that the claims pertaining to them, which were only included in the Amended Complaint filed July 8, 2024, do not relate back to the January 2021 complaint and are thus time barred under the six-year statute of limitation. Docket Nos. 161 at 19; 178 at 16-17.

A. FCA Statute of Limitations

The False Claims Act provides that:

> (b) A civil action under section 3730 may not be brought—
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> > (1) more than 6 years after the date on which the violation of section 3729 is committed, or
> >
> > (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no

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bar was jurisdictional in nature until the FCA was amended through the Patient Protection and Affordable Care Act of 2010."). Thus, the Court first turns to whether the Relator's claims are time barred.

> event more than 10 years after the date on which the violation is committed,
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> whichever occurs last.

31 U.S.C. § 3731(b). Whether the Government elects to intervene in the *qui tam* action does not alter this limitations periods. *Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 587 U.S. 262, 268-69 (2019). "There is no textual basis to base the meaning of '[a] civil action under section 3730' on whether the Government has intervened." *Id.* Thus, the Government's decision not to intervene in the present action does not impact the Court's analysis. *See* Docket No. 17.

Considering the FCA's firm prohibition on filing civil actions "more than 10 years after the date on which the violation is committed" and that this action was commenced on January 8, 2021, at the very least all claims that predate January 8, 2011, are time barred. 31 U.S.C. § 3731(b). The Court continues its analysis as to the claims alleged from January 8, 2011, onward.

Beyond the red line at ten years, the FCA sets an alternate statute of limitations of three-years from when the official of the United States official charged with responsibility to act in the circumstances knew or should have reasonably known of the alleged fraud, "whichever occurs last." 31 U.S.C. § 3731(b)(2). In the context of a *qui tam* action, the § 3731(b)(2) clock begins to run when the Relator provides notice of the events underlying a potential civil action to the United States official charged with responsibility over those matters. *Id.* Who qualifies as an "official of the United States charged with responsibility to act in the circumstances" is not clear from the statutory text alone. However, the statute also grants the Attorney General authority to bring forth civil actions for violations under the FCA. *Id.* § 3731(a). Other district courts have found that § 3731(b)(2)'s "official of the United States charged with responsibility to act," entails "pertinent Department of Justice officials." *United States v. Tech Refrigeration*, 143 F. Supp. 2d 1006, 1009 (N.D.

Ill. 2001) (citing *United States v. Inc. Village of Island Park*, 791 F. Supp. 354, 363 (E.D.N.Y. 1992); *United States v. Macomb Contracting Corp.*, 763 F. Supp. 272, 274 (M.D. Tenn. 1990); *United States v. Macomb Contracting Corp.*, 763 F. Supp. 272, 274 (M.D. Tenn. 1990)). While the Supreme Court affirmatively held that a relator is not an official of the United States under the FCA, it did not provide further guidance as to whom would constitute such an official. *Cochise Consultancy*, 587 U.S. at 272 ("The Government argues that, in [the FCA] context, 'the' official refers to the Attorney General (or his delegate), who by statute 'shall investigate a violation under section 3729.' § 3730(a). Regardless of precisely which official or officials the statute is referring to, § 3731(b)(2)'s use of the definite article 'the' suggests that Congress did not intend for any and all private relators to be considered 'the official of the United States.'"). In the present action, the Relator asserts that he reported the events to the Department of Health and Human Services in February 2019 and to the Federal Bureau of Investigations in July 2019. Docket No. 123 at 4. In light of the above and making all reasonable inferences in favor of the Relator, the Court assumes for purposes of this Opinion and Order that the Relator notified an official of the United States charged with responsibility to act on February 2019. As such, the Relator had three years from February 2019, that is until February 2022, to file the present action.[6] Because the action was filed on January 8, 2021, the FCA action was timely filed and only the claims that predate January 8, 2011, are time barred.

B. Relation Back

CCS argues that the claims asserted against them, which were first brought in the Amended Complaint filed in July 2024, are time barred because (i) the alleged FCA violation

[6] As the Court finds the claims from January 8, 2011, onward to be timely per § 3731(b)(2), the Court need not analyze the alternate six-year statute of limitation provided under § 3731(b)(1).

occurred in August 2015 so the six-year statute of limitations lapsed in August 2021 and (ii) the allegations do not relate back to the original complaint filed in 2021. Docket Nos. 161 at 19; 162 at 9-10; 178 at 17-19. EPR similarly argues that the claims against them do not relate back to the 2021 complaint and are consequently time barred under the FCA's § 3731(b)(2) three-year statute of limitations.

> Since Dr. Nieves sued EPR for the first time through the amended complaint submitted on April 17, 2024 (ECF No. 110) and formally filed on July 8, 2024 (ECF No. 123), the claims against EPR under the FCA are time-barred, as they were brought long after the February 2022 deadline, and they do not relate back to the date this action commenced on January 8, 2021.

Docket No. 178 at 16-17.

Fed. R. Civ. P. 15(c)(1) provides that an amended complaint relates back to the date of the original complaint when:

> **(A)** the law that provides the applicable statute of limitations allows relation back;
>
> **(B)** the amendment asserts a claim or defense that arose out of the conduct, transaction, or occurrence set out—or attempted to be set out—in the original pleading; or
>
> **(C)** the amendment changes the party or the naming of the party against whom a claim is asserted, if Rule 15(c)(1)(B) is satisfied and if, within the period provided by Rule 4(m) for serving the summons and complaint, the party to be brought in by amendment:
>
> > **(i)** received such notice of the action that it will not be prejudiced in defending on the merits; and
> >
> > **(ii)** knew or should have known that the action would have been brought against it, but for a mistake concerning the proper party's identity.

Fed. R. Civ. P. 15(c)(1).

1. EPR

EPR specifically appears in the 2021 complaint when it discusses Sotomonte's alleged "control over emergency room referrals," specifically "that the majority of the referrals to Cardiac Electrophysiologists arising from [the] ER [managed by EPR] [for] unattached patients are made to Dr. Sotomonte." Docket No. 1 at 31. The 2021 complaint also notes that EPR's compensation was increased in 2015 by "more than 180 percent" and that Sotomonte was a signatory to a "2017 contract between EPR and the Hospital, which required the written 'visto bueno' (approval) by the Medical Director." *Id.*

As it pertains to EPR, the Amended Complaint alleges that "Dr. Sotomonte and EPR engaged in an unlawful, systematic scheme where Dr. Sotomonte influenced the contracting processes in the CCCPR by either acquiescing to the contracting of EPR and/or influencing their continuation as service providers and/or increasing the value of their Contract for ER Services, in exchange for patient referrals." Docket No. 123 at 51. Making all reasonable inferences in favor of the Relator, the Court finds that the claims against EPR first raised in the Amended Complaint arise from the same transaction and conduct alleged in the original complaint and, thus, these claims relate back to the original complaint. *See* Fed. R. Civ. P. 15(c)(1)(B).

2. CCS

The claims and conduct allegedly taken by CCS are vaguer in the 2021 complaint and CCS is only mentioned briefly. *See* Docket No. 1 at 30 ("The contract also provided for transfer to Centro Cardiovascular of those patients requiring cardiovascular interventions, including Cardiac Electrophysiology patients. The cardiology services mentioned herein were provided by a private company sub-contracted by Centro Cardiovascular, CCS, PSC."). The 2021 complaint alleges that

"Sotomonte thereby used his power of contracting as a means to secure referrals and to enrich his private Cardiac Electrophysiology practice. When a patient at one of the transferor hospitals required Cardiac Electrophysiological procedures, he or she was referred almost exclusively to Dr. Sotomonte." *Id.* In contrast, the Amended Complaint alleges that

> Dr. Sotomonte engaged in an unlawful, systematic scheme by pushing for or influencing the process by which CCCPR granted to Dr. Jaime Aponte, a recently graduated Cardiology Fellow from the UPR Cardiology Training Program, and his newly created company, CCS, a lucrative contract, in exchange for an illegal compensation arrangement that included patient referrals.

Docket No. 123 at 42. Making all reasonable inferences in favor of the Relator, the Court finds that the claims against CCS in the Amended Complaint arise from the same transaction and conduct set forth in the original complaint and, thus the claims pertaining to CCS relate back to the original complaint under Rule 15(c)(1)(B) and are not time barred.[7]

II. *Res Judicata*

Hernández, Medtronic, Heart Rhythm Management, and Sotomonte argue that the claims against them are barred under the doctrine of *res judicata*.[8] *See* Docket Nos. 134 at 2-3; 162 at 2, 12-17; 181 at 3, 18-21. Defendants direct the Court to *Nieves-Ortiz v. Corporacion de Centro Cardiovascular de Puerto Rico y del Caribe et al.* ("*Nieves I*"), Civ. No. 20-1717 (D.P.R. 2024).[9] The Relator filed *Nieves I*

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[7] Furthermore, EPR and CCS received timely summons only days after the Amended Complaint was filed and they have not been prejudiced in defending on the merits. *See* Docket Nos. 125; 126.

[8] "*Res judicata* is an affirmative defense, but where, as here, the defendant has raised the question on motion to dismiss, the plaintiff does not object to the procedure, and the court discerns no prejudice, the issue may be resolved on such a motion." *Pisnoy v. Ahmed (In re Sonus Networks, Inc.)*, 499 F.3d 47, 56 (1st Cir. 2007) (citations omitted).

[9] *See Kowalski v. Gagne*, 914 F.2d 299, 305 (1st Cir. 1990) ("It is well-accepted that federal courts may take judicial notice of proceedings in other courts if those proceedings have relevance to the matters at hand.") (citations omitted).

in this Court on December 15, 2020. Per Defendants, *res judicata* applies because "virtually all the same parties in this case previously litigated claims arising from the exact same allegations that Relator belatedly urges form the basis of his *qui tam* claims," and that "the parties would reasonably expect to litigate and try Relator's two sets of claims together." Docket No. 162 at 13, 16.

To succeed under a *res judicata* defense, the moving party must show "(1) a final judgment on the merits in an earlier proceeding, (2) sufficient identicality between the causes of action asserted in the earlier and later suits, and (3) sufficient identicality between the parties in the two actions." *Banco Santander de P.R. v. Lopez-Stubbe (In re Colonial Mortg. Bankers Corp.)*, 324 F.3d 12, 16 (1st Cir. 2003). Under the doctrine of *res judicata*, "a final judgment on the merits of an action precludes the parties or their privies from relitigating claims that were raised or could have been raised in that action." *Gonzalez-Pina v. Guillermo Rodriguez*, 407 F.3d 425, 429 (1st Cir. 2005).

In *Nieves I*, Plaintiff brought the following causes of action: (i) retaliation under the FCA, (ii) violations of the Sherman Act's antitrust provisions, (iii) violations of Due Process, and (iv) violations under Puerto Rico's tort law.[10] *Nieves I*, Civ. No. 20-1717, Docket No. 1 at 43, 49, 53, 54. On the other hand, in the instant action, Plaintiff asserts the following FCA claims: (i) presentation of false claims, (iii) use of false statements, and (iii) conspiracy to violate the FCA. Docket No. 123 at 59-65. In *Nieves I*, the claims against Defendants Sotomonte, Heart Rhythm

[10] Final judgment for the purposes of *res judicata* was entered dismissing Plaintiff's claims as to the above listed co-Defendants. *Federated Dep't Stores v. Moitie*, 452 U.S. 394, 399 n.3 (1981) ("The dismissal for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6) is a judgment on the merits.").

Managment, Medtronic, Hernández, and CCCPR were dismissed without prejudice. *Nieves I*, Civ. No. 20-1717, Docket Nos. 90 and 94.

A. FCA Retaliation

In *Nieves I*, the Court dismissed without prejudice the Relator's FCA retaliation claims against Sotomonte and Heart Rhythm Management because Plaintiff could not demonstrate the requisite employer-employee or contractual/agency relationship between the two parties. Civ. No. 20-1717, Docket No. 90 at 4. Nevertheless, for the reasons discussed below, this final judgment on the merits does not preclude the FCA claims currently before this Court.

The retaliation claims, while arising under the same statute, are not substantially similar to the claims asserted in the instant case. "Congress added 31 U.S.C. § 3730(h) to the False Claims Act in 1986 to protect employees who pursue, investigate, or contribute to an action exposing fraud against the government." *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 235 (1st Cir. 2004). A FCA retaliation claim requires a showing "that 1) the employee's conduct was protected under the FCA; 2) the employer knew that the employee was engaged in such conduct; and 3) the employer discharged or discriminated against the employee because of his or her protected conduct." *Karvelas*, 360 F.3d at 235. Crucially, a plaintiff need not prove an underlying fraud to succeed under a FCA retaliation claim. *Id.* at 238 n.23 ("A retaliation claim under 31 U.S.C. § 3730(h) does not require a showing of fraud and therefore need not meet the heightened pleading requirements of Rule 9(b)."); *see also Cochise Consultancy*, 587 U.S. at 269-70 ("[R]etaliation claims need not involve an actual violation of § 3729."). Thus, a FCA retaliation claim is a separate and far more limited cause of action than the FCA fraud claims at issue here,

which have different elements and different pleadings standard.[11] *See Walsh v. Int'l Longshoremen's Ass'n, AFL CIO, Local 799*, 630 F.2d 864, 873 (1st Cir. 1980) (recognizing that *res judicata* did not bar "subsequent conduct [that] was broader and more far reaching than the conduct which led to the original complaint.").

Additionally, the parties in interest here are not sufficiently identical to the parties in the previous action. In *Nieves I*, the Relator is the party at interest with regard to the FCA retaliation claim. By contrast, in a FCA action brought under 31 U.S.C. § 3730(b), the government is the true party of interest. *See United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 425 (2023) ("The Government, after all, is a 'real party in interest' in a *qui tam* action."). Thus, the Relator's FCA retaliation claim does not bar the FCA fraud claims currently pending before the Court.

B. Sherman Act's Antitrust Provisions

Nieves I also dismissed without prejudice the Sherman Act claims against Sotomonte, Heart Rhythm Management, Medtronic, Hernández, and CCCPR.[12] Civ. No. 20-1717, Docket No. 94 at 4. As "the Sherman Act reaches only activities in the flow of interstate commerce or that, 'while wholly local in nature,' would substantially affect interstate commerce if successful," *United States v. Vega-Martínez*, 949 F.3d 43, 48 (1st Cir. 2020), *Nieves I* reasoned that the Relator could not succeed on the claims under Section 1 and 2 of the Sherman Act because he was unable to "connect the antitrust violations in question to interstate commerce." Civ. No. 20-1717, Docket Nos. 94 at

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[11] Furthermore, the statute of limitations for a FCA retaliation claim, 31 U.S.C. § 3730(h), is distinct from those applied to FCA fraud actions by private persons, 31 U.S.C. § 3730(b).

[12] In *Nieves I*, the Court declined to exercise supplemental jurisdiction over the claims brought under Puerto Rico antitrust and tort law, "except for the Puerto Rico tort claims against CCC that stem from the same conduct that gives rise to plaintiff's FCA and due process claims." Civ. No. 20-1717, Docket No. 94 at 8-10.

8; *see also* 15 U.S.C. §§ 1, 2. Despite this final judgment on the merits, there is not sufficient "identity between the causes of action asserted in the earlier" suit with those currently before this Court. *Lopez-Stubbe*, 324 F.3d at 16.

As noted in *Nieves I*, Section 1 of the Sherman Act prohibits the formation of a "contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States," while Section 2 "punishes every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States." Civ. No. 20-1717, Docket Nos. 94 at 4-5 (cleaned up). By contrast, the FCA

> imposes liability upon persons who 1) present or cause to be presented to the United States government, a claim for approval or payment, where 2) that claim is false or fraudulent, and 3) the action was undertaken "knowingly," in other words, with actual knowledge of the falsity of the information contained in the claim, or in deliberate ignorance or reckless disregard of the truth or falsity of that information. 31 U.S.C. § 3729(a)(1), (b).

Karvelas, 360 F.3d at 225. Furthermore, the FCA, unlike the Sherman Act, does not require that the alleged conduct impact interstate commerce nor does it require a showing of "a contract, combination or conspiracy among two or more separate entities" that "unreasonably retrains trade." *Nieves I*, Civ. No. 20-1717, Docket Nos. 94 at 4-5 (cleaned up). Given such glaring distinctions, the Court cannot hold that there is sufficient identicality between the Sherman Act causes of action asserted in the earlier suit and the FCA claims in the present action.

Accordingly, the Court finds that *res judicata* does not bar the claims asserted in this case because there is not sufficient identicality between the causes of action nor sufficient identicality between the parties in both cases.

III. Public Disclosure

Defendants Hernández, Medtronic, CCCPR, Heart Rhythm Management, and Sotomonte also argue that the claims are barred under the doctrine of public disclosure. Docket Nos. 134 at 3; 162 at 17-21; 180 at 3; 181 at 21-24. The FCA's public disclosure bar provides that courts shall not entertain a "qui tam action that is based upon a prior 'public disclosure of allegations or transactions' found in any of a number of statutorily specified sources." *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 719 F.3d 31, 33 (1st Cir. 2013). Exceptions are carved out for those who are an "original source of the information in question." *Id.* at 34; *see also Karvelas*, 360 F.3d at 225-26 ("An FCA *qui tam* action may not be based on publicly disclosed information unless the relator is the original source of that information.") (cleaned up). Original sources are persons who "(1) have direct and independent knowledge of the information supporting [their] claims that (2) [they] provided . . . to the Government before filing an action." *Duxbury*, 719 F.3d at 34 (citations omitted). "This language excludes individuals who must rely upon information already in the possession of the government to adequately state their claim." *Karvelas*, 360 F.3d at 230. Such information includes "allegations or transactions . . . in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation," including "a federal agency's written response to a request for records under the Freedom of Information Act." *Schindler Elevator Corp. v. United States ex rel. Kirk*, 563 U.S. 401, 404 (2011) (cleaned up). "The public disclosure bar provides a broad sweep." *Id.* at 408. Here, making all reasonable inferences in the Relator's favor, the Court finds that Plaintiff has sufficiently alleged (i) direct and independent knowledge as to the alleged kickback scheme ostensibly orchestrated to defraud the government, and (ii) that the Relator provided this information to the government prior to filing. Thus, the

claims are not barred under the doctrine of public disclosure, and the Court turns to Rule 9(b)'s heightened pleading standards.

IV. The FCA and Rule 9(b)'s Heightened Pleading Standards

Allegations of fraud must be sufficiently particularized in accordance with Fed. R. Civ. P. 9(b) to survive a motion to dismiss. *Rodi v. S. New Eng. Sch. of Law*, 389 F.3d 5, 15 (1st Cir. 2004). "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "The particularity requirement means that a complaint must specify the time, place, and content of an alleged false representation." *United States ex. rel. Kelly v. Novartis Pharms. Corp.*, 827 F.3d 5, 13 (1st Cir. 2016) (cleaned up); *see also Rodi*, 389 F.3d at 15 ("The other elements of fraud, such as intent and knowledge, may be averred in general terms."). In the case at hand, Relator asserts three claims of fraud under the FCA: (1) presentation of false claims, (2) use of false statements, and (3) conspiracy to violate the FCA. Docket No. 123. Rule 9(b) applies to these FCA claims. *Karvelas*, 360 F.3d at 228 ("[E]very circuit court that has addressed this issue has concluded that the heightened pleading requirements of Rule 9(b) apply to claims brought under the FCA.") (collecting cases); *see also United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 731 (1st Cir. 2007).

Rule 9(b) requires that claims of fraud under the FCA be "stated with particularity" and that the pleadings should "specify[] the 'time, place, and content' of the alleged false or fraudulent representations." *Karvelas*, 360 F.3d at 232. Courts are reluctant "to permit qui tam relators to use discovery to meet the requirements of Rule 9(b)" as "qui tam plaintiff, who has suffered no injury in fact, may be particularly likely to file suit as a pretext to uncover unknown wrongs." *Id.* at 231. "A qui tam relator may not present general allegations in lieu of the details of actual false claims

in the hope that such details will emerge through subsequent discovery." *Id.* The Relator "must provide details that identify particular false claims for payment that were submitted to the government." *Id.* Such details include "dates of claims, identification numbers, or amounts charged to the government"; failure to provide specific details to identify particular false claims is fatal to a relator's case. *Rost*, 507 F.3d at 732 (citing *Karvelas*, 360 F.3d at 232). "Evidence of an actual false claim is the *sine qua non* of a False Claims Act violation." *Karvelas*, 360 F.3d at 225; *see also Guilfoile v. Shields*, 913 F.3d 178, 188 (1st Cir. 2019) ("In a suit directly alleging the submission of a false claim, a plaintiff must sufficiently plead facts supporting the existence of an actual false claim.").

The FCA is only triggered once a false claim for payment is submitted to the government. *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995). Allegations of fraud or schemes to defraud the government alone cannot trigger the FCA unless paired with the existence of an actual false claim. The alleged false claim must also be "material," meaning it must have "a natural tendency to influence or was capable of influencing the government's decision whether to pay or reimburse the claim." *Guilfoile*, 913 F.3d at 187 (citation omitted). This materiality requirement is "demanding" and requires that "a plaintiff directly alleging the submission of a false claim must plead facts to support allegations of materiality with 'plausibility and particularity.'" *Id.* (cleaned up). Additionally,

> [t]he FCA includes a scienter requirement that the false claim be submitted "knowingly." A "non-submitting" entity that knowingly causes the submission of a false claim may be liable under the FCA even if the entity directly submitting the claim to the government lacks the requisite mental state.

Id. (citations omitted). Nevertheless, "in 2010, the AKS was amended to create an express link to the FCA. The AKS now provides that a claim that includes items or services resulting from

a violation of this section constitutes a false or fraudulent claim for purposes of the FCA." *Id.* at 189 (cleaned up). In other words, "if there is a sufficient causal connection between an AKS violation and a claim submitted to the federal government, that claim is false within the meaning of the FCA." *Id.* at 190.

In *United States v. Regeneron Pharms., Inc.*, the First Circuit recently opined on "the proper standard of causation required to turn an AKS kickback into a per se FCA violation." 128 F.4th 324, 327 (1st Cir. 2025). The First Circuit affirmed the lower court's finding "that to treat an AKS violation as a false claim under the FCA, the government must prove that the AKS violation was a but-for cause of the false claim." *Id.* at 328. "If the government can show that the illicit kickback was a but-for cause of the submitted claim, then the claim is 'per se false' even absent a false certification of AKS compliance." *Id.* at 335.

The Amended Complaint claims that, while he worked for Medtronic, Hernández "bribed referring physicians to send patients to Dr. Sotomonte" with the intention that "Dr. Sotomonte would implant Medtronic EMDs and bill many, if not most, of those procedures to Federal Health Care Programs." Docket No. 138 at 28; *see also* Docket No. 123 at ¶¶ 72, 119-20, 129, 159. Per Relator, "Sotomonte and the CCCPR must have certified their compliance with all applicable laws and regulations, including the AKS, when filing reimbursement claims," and therefore "it is more than reasonable to infer that Dr. Sotomonte and the CCCPR filed—and that Medtronic and Hernández caused them to file—false claims for reimbursement to the Federal Health Care Programs in violation of the FCA." Docket No. 138 at 28. Additionally, the Relator argues that "there is also no question that at least one purpose of the payments from CCCPR to CCS under the Transfer Program contracts were to induce patient referrals, because Dr. Sotomonte himself explained that the purpose of the transfer program was to increase referrals to the CCCPR." Docket No. 176 at

28. On the other hand, Defendants counter that "assuming as true that these federal programs did disburse payments to CCCPR and/or Sotomonte for DCH patient treatment (which in and of itself is speculative at this point because the Relator has not provided these essential details of these alleged payments)," and there remains the potential that there were other legitimate reasons for payment. Docket No. 185 at 8-9. Defendants continue "as per the Relators blanket contentions, each and every claim allegedly submitted by CCCPR to any federal health program, was false, simply because the Relator believes that they were product of a patient transfer performed under the contract between CCS and CCCPR." *Id.* Defendants additionally underscore that the Amended Complaint "fails to present a single claim with a single specific date and a single name of a physician who Hernández allegedly induced to refer a single Medicare or Medicaid patient to Dr. Sotomonte in exchange for something of value." Docket No. 134 at 4. As CCS summarizes,

> [T]he alleged kick-back scheme is not well pleaded, insofar as (i) it fails to provide the required details needed for such a claim, (ii) the Relator does not allege which patients were referred as part of the alleged scheme, (iii) he does not provide any statistical allegations as to what portion of the patients cared for at DCH were unnecessarily transferred vis-a-vis patients whose transfers were bona fide, (iv) it does not provide percentage or statistical allegations that any federal health program actually paid a claim product of the alleged scheme, making it more probable that such incidents would repeat themselves, (v) the Relator does not provide any statistical or percentage allegations on the total number of claims submitted or caused to be submitted to federal health care programs vis-a-vis, the possible number of claims that were supposedly fraudulent.

Docket No. 185 at 7. The Court agrees. The Amended Complaint does not comply with the heightened pleading standard in Rule 9(b) because it is devoid of any information as to any allegedly fraudulent claim submitted to the government. The Relator fails to specifically identify a single claim that was fraudulently submitted, nor has he provided any factual allegations as to any claim submitted by Defendants.

The Relator insists that "Rule 9(b) does not require [him] to plead specific false claims," and cites *United States ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71 (2d Cir. 2017), in support of his position. Docket No. 138 at 22. While the Second Circuit found that Rule 9(b)'s requirements must not be adopted too stringently as to render FCA toothless, it still required "pleading of the circumstances of the alleged fraud with a certain amount of precision that serves Rule 9(b)'s purpose by apprising the defendant of the nature of the claim the acts or statements or failures to disclose relied upon by the plaintiff as constituting the fraud being charged." *Chorches*, 865 F.3d at 86-87 (cleaned up).

In *Chorches*, the plaintiff pleaded "details [as to] the specifics of a scheme whereby [the defendant] falsified [Patient Care Reports] so as to certify runs as 'medically necessary' and thus render them reimbursable by the government." *Id.* at 83. The allegations in *Chorches* included "not only the time period of [the plaintiff's] employment, August 2010 to December 2011, as that during which the fraudulent scheme took place, but also provide[d] dates, both precise and approximate, with respect to many particular runs for which [the plaintiff] was later asked to falsify a [Patient Care Report]." *Id.* The *Chorches* complaint also included "patient names, actual reasons for the transport[,] and information entered into [Patient Care Reports]." *Id.* at 87. The Second Circuit found that there were "ample details as to the nature of the alleged scheme, as well as to *particular instances in which the scheme was, to the personal knowledge of the original relator, allegedly carried out*," to place defendants on notice as to the "specific claims allegedly submitted to the government." *Id.* (emphasis added). By contrast, the Relator in this case has not provided any such specificity. The Amended Complaint does not provide any specific dates as to when the alleged fraudulent claims for payment were submitted. Nor does it allege that the fraudulent claims were submitted in any

limited time frame. Rather, the Amended Complaint seems to allege that Defendants submitted or induced the submission of fraudulent claims unceasingly since at least July 2011. *See* Docket No. 123 at 28.

Lacking specific identifying details, the Court finds that while the Relator's factual averments may "suggest fraud was possible," the Amended Complaint "contain[s] no factual or statistical evidence to strengthen the inference of fraud beyond possibility." *Rost*, 507 F.3d at 733. Thus, the Relator has failed to plead his FCA claims with the specificity required under Rule 9(b). The Court concurs that "the contentions are espoused in such a vague and non-specific manner," which "fail[s] to comply with the provisions of Rule 12(b)(6) and Rule 9(b)." Docket No. 161 at 25. In light of the above, the Court finds that the Relator has failed to assert sufficient facts as to the alleged fraud schemes. This is fatal to Relator's claims.

CONCLUSION

For the aforementioned reasons, the Relator's Amended Complaint fails to comply with the heightened pleading standard in Rule 9(b). Accordingly, the Amended Complaint is hereby **DISMISSED WITH PREJUDICE**. Judgment shall be entered accordingly.

IT IS SO ORDERED.

In San Juan, Puerto Rico, this Monday, March 31, 2025.

s/ Jay A. Garcia-Gregory
JAY A. GARCIA-GREGORY
United States District Judge